

### **REMARKS**

Claims 1, 2, 5-10, 29-35, 37, 38, 40, and 62-65 are pending. Claims 3, 4, 11-28, 36, 39, 41-61, 66, and 67 have been previously cancelled without disclaimer or prejudice. Claims 1, 29, 31-34, 37, 40, and 65 have been amended. Support for the amendments can be found throughout the specification and claims as originally filed. In particular, support for the amendments can be found in the specification at page 4, lines 8-10. Accordingly, no new matter has been introduced by the amendments.

#### **Rejections under 35 U.S.C. § 102**

##### ***Eckerson (U.S. Patent No. 4,865,048)***

Claims 1, 2, 10, 32, and 40 are rejected under 35 U.S.C. § 102(b) as being anticipated by Eckerson (U.S. Patent No. 4,865,048). Applicants traverse the rejection. Without acquiescing to the basis of the rejection and solely to facilitate allowance of the claims, claims 1, 29, 31, 32-34, 37, 40, and 65 have been amended. As amended, the claims are directed to a method of treating nausea and/or vomiting caused by pregnancy, motion sickness, or chemotherapy comprising the steps of stimulating the vagus nerve in the neck of a patient. Eckerson teaches a method of treating the symptoms associated with acute alcohol or drug withdrawal by delivering a very specific electromagnetic waveform to the mastoid process (See Eckerson, Abstract). Eckerson does not provide for treating nausea and/or vomiting caused by pregnancy, motion sickness, or chemotherapy; therefore, Eckerson does not anticipate the amended claims. Furthermore, Eckerson does not provide for stimulating the vagus nerve because the mastoid process is not innervated by the vagus nerve; instead the mastoid process is innervated by nerves from the cervical portion of the spinal cord. Accordingly, Applicants respectfully request that the rejection be withdrawn.

##### ***Marchal et al. (U.S. Patent No. 6,853,862)***

Claims 1, 2, 5, 29, 30, 40, and 62-64 are rejected under 35 U.S.C. § 102(e) as being anticipated by Marchal et al. (U.S. Patent No. 6,853,862). Applicants traverse the rejection. Without acquiescing to the basis of the rejection, and solely to facilitate allowance, Applicants have amended claims 1, 29, 31, 32-34, 37, 40, and 65. As amended the claims are directed to a

method of treating nausea and/or vomiting by stimulating the vagus nerve in the neck of a patient. Marchal et al. provide for stimulating the nerves that innervate the pancreas in order to treat nausea and or vomiting by influencing pancreatic secretions (See Marchal et al., Abstract). Because Marchal et al. do not provide for stimulating the vagus nerve in the neck of a patient, Marchal et al. do not anticipate the claims as amended. Indeed, Marchal et al. specifically teach away from the claimed method by stating that vagal stimulation is difficult to achieve and can adversely stimulate other organs, and that vagal stimulation can cause damage to the vagus nerve (See Marchal et al., col. 1, lines 48-51). Accordingly, Applicants respectfully request that the rejection be withdrawn.

### **Rejections under 35 U.S.C. § 103**

#### ***Eckerson (U.S. Patent No. 4,865,048)***

Claims 5-9 and 62 are rejected under 35 U.S.C. § 103(a) as being obvious in light of Eckerson. Applicants respectfully disagree. Eckerson teaches a method of treating the symptoms of acute alcohol and drug withdrawal by stimulating the mastoid process (See Eckerson, Abstract). One of the many symptoms of acute alcohol and drug withdrawal taught by Eckerson is vomiting (See Eckerson, col. 2, lines 57-64). As discussed above, Applicants have amended the claims so that they are directed to treating nausea and/or vomiting caused by pregnancy, motion sickness, or chemotherapy. Eckerson teaches a method of alleviating the symptoms of acute alcohol and drug withdrawal and not treating nausea or vomiting *per se*. Indeed, Eckerson does not even mention nausea as a symptom of acute alcohol and drug withdrawal. Further, as discussed above, Eckerson does not teach stimulating the vagus nerve because the mastoid process is not innervated by the vagus nerve. There is no teaching or suggestion in Eckerson that stimulating the vagus nerve in the neck would be useful for treating nausea and/or vomiting caused by pregnancy, motion sickness, or chemotherapy. Therefore, Eckerson does not render the amended claims obvious.

***Marchal et al. (U.S. Patent No. 6,853,862)***

Claims 6-9, 31, 33, and 65 are rejected under 35 U.S.C. § 103(a) as being obvious in light of Marchal et al. Applicants respectfully disagree. Claims 1, 29, 31-34, 37, 40, and 65 have been amended.

As amended the claims are directed to a method of treating nausea by stimulating the vagus nerve in the neck of a patient. Marchal et al. teach treating nausea and vomiting by directly stimulating the nerves that innervate the pancreas. Marchal et al. do not teach or suggest stimulating the vagus nerve in the neck as a means of treating nausea and/or vomiting. Moreover, as discussed above, Marchal et al. specifically teach away from the claimed method of stimulating the vagus nerve (See Marchal et al., col. 1, lines 48-51).

Claims 10 and 32 are rejected under 35 U.S.C. § 103(a) as being obvious over Marchal et al. in view of Barrett et al. (U.S. Patent No. 6,609,025). In particular, the Examiner alleges that Marchal et al. does not teach electrodes placed on the skin but that Barrett et al. teaches that the vagus nerve may be stimulated non-invasively. Applicants respectfully disagree. Marchal et al. teach directly stimulating the nerves that innervate the pancreas by implanted electrodes. Barrett et al. does not cure the deficiencies in Marchal et al. because Barrett et al. teaches indirectly stimulating the vagus nerve at a subdiaphragmatic location (See Barrett et al., col. 7, lines 64-67) and, therefore, neither Marchal et al. nor Barrett et al. either individually or in combination teach stimulating the vagus nerve in a patient's neck. Further, as discussed above, Marchal et al. teach away from stimulating the vagus nerve as in the claimed method (See Marchal et al., col. 1, lines 48-51).

Claims 34, 35, 37, and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Marchal et al. in view of Bertolucci (U.S. Patent No. 4,981,146). In particular, the Examiner admits that Marchal et al. do not explicitly provide for a method of treating chemotherapy patients or those suffering from motion sickness. However, the Examiner alleges that common sense would indicate that a method of treating nausea in pregnant women would be capable of reducing nausea and/or vomiting in a patient undergoing chemotherapy or suffering from motion sickness. Applicants respectfully disagree. Marchal et al. only teaches a method of treating nausea and vomiting by stimulating the nerves that innervate the pancreas. Moreover,

Marchal et al. provides a specific discussion of the types of nausea and vomiting that can be treated by stimulating the pancreas, namely those resulting from an osmotic imbalance which can be targeted by stimulating the pancreas (See Marchal et al., col. 6, line 39 to col. 7, line 12). Given the specific osmotic imbalance underlying the nausea and vomiting of pregnancy, it is not common sense that stimulating the pancreas would be useful for treating nausea and vomiting caused by chemotherapy and motion sickness. Bertolucci does not cure the deficiency in Marchal et al. because Bertolucci does not teach that stimulating the nerves that innervate the pancreas would treat nausea and vomiting resulting from chemotherapy or motion sickness. Instead, Bertolucci teaches treating chemotherapy patients or people suffering from motion sickness by the stimulation of the P6 or master point in the wrist (see Bertolucci, col. 2, lines 23-25). Indeed, the teaching of Bertolucci is so distinct from that of Marchal et al. that there would be no motivation to combine the teachings. Furthermore, neither Marchal et al. nor Bertolucci either individually or in combination teach stimulating the vagus nerve in the neck to treat nausea or vomiting resulting from chemotherapy or motion sickness. Additionally, as discussed above Marchal et al. teach away from stimulating the vagus nerve in the neck as in the claimed invention (See Marchal et al., col. 1, lines 48-51). Accordingly, Applicants respectfully request that the rejection be withdrawn.

**CONCLUSION**

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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